CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY
DEPARTMENT OF PESTICIDE REGULATION
MEDICAL TOXICOLOGY BRANCH

SUMMARY OF TOXICOLOGY DATA
NONANOIC ACID (PELARGONIC ACID)

Chemical Code # 002739, DPN # 51824
Original date: February 25, 2005

I. DATA GAP STATUS

Chronic toxicity, rat:	Data gap, no study on file.
Chronic toxicity, dog:	Data gap, no study on file.
Oncogenicity, rat:	Data gap, no study on file.
Oncogenicity, mouse (dermal)	Data gap, inadequate study on file, no adverse systemic effect.
Reproduction, rat:	Data gap, no study on file.
Teratology, rat:	Data gap, inadequate study, no adverse effect indicated.
Teratology, rabbit:	Data gap, no study on file.
Gene mutation:	No data gap, possible adverse effect
Chromosome effects:	No data gap, no adverse effect .
DNA damage:	Data gap, no study on file..
Neurotoxicity:	Not required at this time.

Toxicology one-liners are attached.

All record numbers through 155361 were examined.
** indicates an acceptable study.
Bold face indicates a possible adverse effect.

File name: T050225
Original: J. Kishiyama and Gee, 2/25/05

The US Environmental Protection Agency has exempted nonanoic acid from tolerances, based on use patterns, natural occurrence and known toxicity.
In a memorandum dated February 9, 1994, staff from the California Office of Environmental Health Hazard Assessment agreed that the studies for the remaining data gaps could be waived. This is in essential agreement with the US EPA.

II. TOXICOLOGY ONE-LINERS AND CONCLUSIONS

These pages contain summaries only. Individual worksheets may contain additional effects.

COMBINED, RAT

No study submitted.

51824 016 154910 "Range-Finding for a 90-Day Rat Oral Toxicity (Diet)." (J. O. Kuhn; Stillmeadow, Inc., Sugar Land, TX; Study No. 1941-95; 8/29/95). Three rats/sex/group received pelargonic acid (purity: 93%) in the diet at doses of 0, 1500, 2500, 4000, 6300, 7500, and 10000 ppm for 3 weeks (note: last dose level was raised to 20000 ppm after the first week) (test material consumption: 0, 145, 267, 423, 633, 753, and 1016 (1st week) and 1834 (2nd and 3rd weeks) mg/kg/day, respectively). No mortality resulted from the treatment. No apparent treatment-related effects upon mean body weights, hematological or serum chemical parameters. Gross examination of the tissues did not reveal any treatment-related lesions. No adverse effects indicated. **NOEL:** 20,000 ppm (1834 mg/kg/day); **Study supplemental** (non-guideline study). (Moore, 6/17/97)

51824 - 0023 155340 US EPA DER for record 154910. Study evaluated as unacceptable. A 90-day study was being required (1996). (Gee, 2/25/05)

No record number. "Pelargonic acid (nonanoic acid); exemption from the requirement of a pesticide tolerance." (Federal Register 68 (33): 7931, February 19, 2003) This "final rule" states on page 7932 that the 90-day oral study is not necessary, in contrast to the DER of 1996.

CHRONIC TOXICITY, DOG

No study submitted.

ONCOGENICITY, MOUSE

51824 - 017 154911 "Chronic mouse dermal study." (W. Barkley *et al.*, Kettering Laboratory, University of Cincinnati, OH, No. 7/85) C182 (pelargonic acid) was tested at 50 mg twice weekly for 80 weeks. A negative control group (mineral oil) and a positive control (50 mg benzo(a)pyrene were included with 50 male mice per group. No dermal or systemic effects were seen with pelargonic acid. (Adapted from Moore, 6/17/97) (Gee, 2/25/05)

51824 - 0023 155343 US EPA DER for 154911, evaluating the above study as supplementary but sufficient to grant a waiver for a 90-day dermal toxicity study (Gee, 2/25/05).

REPRODUCTION, RAT

No study submitted.

TERATOLOGY, RAT

51824 018; 154912 "Teratology Screen in Rats." (A. E. Wakefield, Hazleton Washington, Inc., Vienna, VA; Study No. HWA 2689-101; 4/22/94). Twenty two pregnant female rats were dosed

orally by gavage with corn oil alone or 1500 mg/kg of C-182 (pelargonic acid) (purity not reported) from day 6 through day 15 of gestation. No mortalities resulted from the treatment. No treatment-related signs were noted for the dams. No apparent effects upon fetal development were evident. The four offspring of one treated dam which suffered from a cleft palate appeared to be suffering from a developmental problem unrelated to the test material. No adverse effect indicated. **NOEL:** 1500 mg/kg. **Study supplemental** (study as a screen and not according to guidelines). (Moore, 6/17/97)

51824 - 0023 155344 US EPA DER for 154912, evaluating the study as acceptable with a LOEL > 1500 mg/kg/day.

TERATOLOGY, RABBIT

No study submitted.

GENE MUTATION

** 51824 - 0020 155328: Lawlor, T. E. "Mutagenicity Test on Pelargonic Acid (Technical Grade) in the *Salmonella*/Mammalian-Microsome Reverse Mutation Assay (Ames Test)." (Hazleton Washington, Incorporated, HWA Study No.: 15656-0-401R, November 29, 1993) Pelargonic acid (Technical Grade) was evaluated for mutagenicity at concentrations ranging from 6.67 to 5000 µg/plate with and without metabolic activation from Sprague-Dawley rat livers using *Salmonella typhimurium* strains TA98, TA 100, TA1535, TA1537 and TA1538 with triplicate plates per concentration. Pelargonic acid treatments (with and without S9 Mix) under study (initial and confirmatory) conditions did not significantly increase the number of revertants. ACCEPTABLE . (Kishiyama and Gee, 2/23/05).

51824 - 0023 155339 US EPA DER for 155328.

** 51886 - 002 123892 San, R. H. C. and C. Kruel. "*Salmonella*/Mammalian-Microsome Plate Incorporation Mutagenicity Assay (Ames Test)." **(**Microbiological Associates, Incorporated, Laboratory Study No. T8769.501, August 29, 1989.) n-Pelargonic Acid (98.5%) was evaluated for mutagenicity at concentrations of 0, 667, 1000, 3333, 6667 and 10000 µg/plate with and without rat liver metabolic activation using *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538. There were triplicate plates in two trials. Pelargonic Acid treatment (with and without S9 Mix) under study conditions did not significantly increase the number of revertants. ACCEPTABLE. (Kishiyama and Gee, 2/23/05).

**** 51824 - 022 155330** Cifone, M. A. "Mutagenicity Test on Pelargonic Acid (Technical Grade) in the L5178Y TK+/- Mouse Lymphoma Forward Mutation Assay with a Confirmatory Assay **.**" **(**Hazleton Washington, Incorporated, HWA Study No.: 15656-0-431R, September 14, 1993) Pelargonic Acid (Technical Grade) was evaluated for mutagenicity at concentrations ranging from 150 to 1600 µg/ml without activation and from 37.5 to 600 µg/ml with rat liver activation with 4 hours of exposure of L5178Y TK +/- cells. The pH of the cell cultures was adjusted to neutral pH for testing. A concentration of 2000 ug/ml was stated to be "highly toxic." Pelargonic Acid treatment with activation significantly induced forward mutation at the thymidine kinase locus in mouse lymphoma L5178Y cell line with the increase primarily in small colonies. Positive controls were functional. ACCEPTABLE. (Kishiyama and Gee, 2/24/05).

51824 - 0023 155337 US EPA DER for 155330.

CHROMOSOME EFFECTS

** 51824 - 021 155329 Murli, H. "Mutagenicity Test on n-Pelargonic Acid *In Vivo* Mouse Micronucleus Assay." (Hazleton Washington, Incorporated, HWA Study No.: 15656-0-455CO, November 17, 1993.) n-Pelargonic Acid was evaluated for the potential to induce micronuclei in bone marrow polychromatic erythrocytes of ICR mice. n-Pelargonic Acid was administered via a single gavage at doses of 0 (corn oil), 1250, 2500, and 5000 mg/kg to 5 mice/sex/sacrifice time at 24, 48, and 72 hours post-dosing. Dosing solutions were analyzed. One thousand PCEs were scored per animal and the PCE/NCE determined. n-Pelargonic acid did not significantly increase micronuclei in bone marrow polychromatic erythrocytes. The positive control was functional. ACCEPTABLE. (Kishiyama and Gee, 2/23/05).

51824 - 0023 155338 US EPA DER for 155329.

DNA DAMAGE

No study submitted.

NEUROTOXICITY

Not required at this time.